S AO 120 (Rev. 2/99)		
TO: Mail Stop 8 Director of the U.S P Alexand	S. Patent & Trademark Offic P.O. Box 1450 Iria, VA 22313-1450 U.S. PAT	REPORT ON THE
		S.C. § 1116 you are hereby advised that a court action has been
		et of California on the following X Patents or Trademarks:
DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
CV 08-03139 WDB	July 2, 2008	Northern District of California, 1301 Clay Street, RM 400S, Oakland, CA 94612
PLAINTIFF CORBETT LIFE SCI		DEFENDANT  APPLERA CORPORATION
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 6,814,934		See Attached
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In the abo	ove—entitled case, the following p	patent(s) have been included:
	☐ Ame	endment
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		See Attached
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In the abo	ve—entitled case, the following d	lecision has been rendered or judgement issued:
CLERK	I (DV)	DEPUTY CLERK DATE
Richard W.		DEPUTY CLERK DATE

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- 52. Upon information and belief, Dr. Higuchi worked with Dr. Dollinger and had knowledge of this machine. In a 2005 article he co-authored, Dr. Higuchi described working with Dr. Dollinger in the development of real-time PCR. This article, entitled "Fifty Years of Molecular (DNA/RNA) Diagnostics" is attached hereto as Exhibit G. In the article Dr. Higuchi describes using a machine the same as described in Example VIII of the '934 patent, to demonstrate real-time PCR. (See, e.g., Exhibit G, page 2, right column.)
- 53. Upon information and belief, this article was received on November 11, 2004, accepted on December 14, 2004, and first published online on January 13, 2005. The '934 patent issued on November 9, 2004.
- 54. An intent to deceive the USPTO can be inferred from the fact that Dr. Higuchi signed a declaration claiming to be the sole inventor of the '934 patent, then nearly simultaneous with the issuance of that patent, he co-authored and submitted an article for publication that described working with Dr. Dollinger and using a machine of the same design as Dr. Dollinger's to demonstrate real-time PCR.
- 55. An intent to deceive the USPTO can be inferred from the fact that the '934 patent specification includes disclosure of Dr. Dollinger's initial design of a real-time PCR machine (described above at ¶¶ 38-45) that fulfills the requirements of claims 1 and 7 but the material information of Dr. Dollinger's independent conception of this machine was not disclosed to the USPTO.
- 56. An intent to deceive the USPTO can be inferred from the fact that the '934 patent specification includes disclosure of Dr. Dollinger's design and construction of a real-time PCR machine (described above at ¶¶ 46-51) that fulfills the requirements of claims 1 and 7 but the material information of Dr. Dollinger's independent conception and reduction to practice of this machine was not disclosed to the USPTO.
- 57. A judicial determination and declaration of unenforceability is necessary and appropriate to resolve this controversy and so that the parties may ascertain their respective rights and duties.

# JURY DEMAND

58. Under Rule 38(b) of the Federal Rules of Civil Procedure, Corbett respectfully requests a jury trial on all issues and claims.

## PRAYER FOR RELIEF

WHEREFORE, Corbett prays for judgment against Applera, and that the Court award the following relief:

- A. Declare that Corbett does not infringe and has not infringed, either directly or indirectly, any valid and enforceable claim of the '934 patent, either literally or under the doctrine of equivalents;
  - B. Declare that the claims of the '934 patent are invalid;
  - C. Declare that the claims of the '934 patent are unenforceable;
  - D. Find this case exceptional and award Corbett its attorneys' fees under 35 U.S.C. § 285;
  - E. Award Corbett its expenses and costs incurred in this action;
- F. Enjoin Applera, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Applera from threatening to assert or otherwise attempting to enforce the '934 patent against Corbett, its customers, suppliers, or anyone in privity with Corbett and from representing to anyone, either directly or indirectly, that Corbett has infringed or is infringing, directly or indirectly, the '934 patent; and
  - G. Such other and further relief as this Court deems just and proper.

Bv:

20 Dated: June 30, 2008

Respectfully submitted,

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CORBETT LIFE SCIENCE,
CORBETT ROBOTICS INC., and

CORBETT RESEARCH PTY LTD.

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12	CORBETT RESEARCH PTY LTD.		
. 13			
14	UNITED STATES DISTRICT COURT WDB		
15	NORTHERN DISTRICT OF CALIFORNIA		
16	CV 08 3139		
17	CORBETT LIFE SCIENCE; ) Case No. CORBETT ROBOTICS INC.; and )		
18	CORBETT ROBOTICS INC., and CORBETT RESEARCH PTY LTD., COMPLAINT FOR DECLARATORY JUDGMENT		
19	Plaintiffs, ) DEMAND FOR JURY TRIAL		
20	vs. )		
21	APPLERA CORPORATION and APPLIED		
22	BIOSYSTEMS,		
23	Defendants. )		
24			
25	Plaintiffs Corbett Life Science, Corbett Robotics Inc. ("Corbett Robotics"), and Corbett		
26	Research Pty Ltd. ("Corbett Research") (collectively "Corbett") complain against Defendants Applera		
27	Corporation and Applied Biosystems Inc. (collectively "Applera"), demand a jury trial, and allege as		
28	follows:		
HOWREY LLP	COMPLAINT FOR DECLARATORY JUDGMENT		

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NATURE OF THE ACTION

1. In this action, Corbett seeks a declaratory judgment of non-infringement, invalidity, and/or unenforceability of Applera's U.S. Patent No. 6,814,934, ("the '934 patent") pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., the patent laws of the United States, 35 U.S.C. § 1, et seq., and other such relief as the Court deems just and proper.

### **PARTIES**

- 2. Plaintiff Corbett Life Science is a corporation organized and existing under the laws of Australia, having its principal place of business in Mortlake, NSW, Australia.
- 3. Plaintiff Corbett Research is a wholly-owned subsidiary of Corbett Life Science organized and existing under the laws of Australia, having its principal place of business in Mortlake, NSW, Australia.
- 4. Plaintiff Corbett Robotics is a wholly-owned subsidiary of Corbett Life Science and a corporation organized and existing under the laws of California, having its principal place of business at 185 Berry Street, Suite 5200, San Francisco, California.
- 5. Upon information and belief, Defendant Applera Corporation is a Delaware Corporation with its principal place of business at 301 Merritt 7, Norwalk, Connecticut.
- 6. Upon information and belief, Defendant Applied Biosystems Inc. is an operating group of Applera Corporation with its principal place of business at 850 Lincoln Centre Drive, Foster City, California.

# JURISDICTION AND VENUE

- 7. This Court has jurisdiction over the subject matter of this action because it seeks a declaratory judgment under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 and 35 U.S.C. § 101 et seq. regarding an actual and justiciable controversy between the parties hereto over whether the '934 patent is valid, infringed, and enforceable.
- This Court has personal jurisdiction over Applera because upon information and belief, 8. Applera Corporation and Applied Biosystems reside in and/or engage in significant business activities in this district, including maintaining offices in this district, employing corporate representatives in this

district, selling products in this district, soliciting business in this district, targeting customers in this
district, and/or deriving substantial revenue from this district, among other things.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(a), 1391(b), 1391(c) and/or 28 U.S.C. § 1400(b) because, upon information and belief, Applied Biosystems and Applera Corporation reside in and/or engage in significant business activities in this district.

# **FACTUAL BACKGROUND**

### APPLERA'S INFRINGEMENT ALLEGATIONS AGAINST CORBETT'S PRODUCTS

- 10. Plaintiff Corbett Life Science is the Australian parent company of a group of biotechnology companies, including plaintiffs Corbett Research and Corbett Robotics, that design, manufacture and internationally distribute instrumentation systems for the life sciences. Corbett's most recognized products are the world's first rotary real-time DNA amplification systems called "Rotor-Gene<sup>TM</sup>."
  - 11. Corbett currently sells its Rotor-Gene<sup>TM</sup> products in the United States.
- 12. Upon information and belief, Applera is the assignee of record of U.S. Patent No. 6,814,934 B1 entitled "Instrument For Monitoring Nucleic Acid Amplification" (the "934 patent"), which was filed on November 12, 1997, and issued on November 9, 2004. The sole inventor named on the '934 patent is Russell Gene Higuchi. A copy of the '934 patent is attached hereto as Exhibit A.
- 13. Upon information and belief, Applera is the exclusive authorized and registered proprietor of European Patent EP 0 872 562 B1 entitled "Instrument for monitoring nucleic acid amplification reactions," (the "562 EP"). A copy of the '562 EP is attached hereto as Exhibit B.
- 14. The sole inventor named on the '562 EP is Russell Gene Higuchi, who is the same sole inventor named on the '934 patent.
- 15. The priority patent application listed on the '562 EP is United States patent application 695,201, filed May 2, 1991, which is the identical priority patent application as listed on the '934 patent.
- 16. The language of claim 1 of the '934 patent is nearly identical to the language of claim 1 of the '562 EP. A chart comparing the claim language is attached hereto as Exhibit C.

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COMPLAINT FOR DECLARATORY JUDGMENT

- 17. On March 28, 2008, Applera's counsel sent Corbett a letter under the subject heading "Infringement of patent EP 0 872 562 by the Rotor-Gene 3000 and Rotor-Gene 6000," which is attached as Exhibit D.
- 18. In the letter, Applera's counsel stated: (1) the features of claim 1 of the '562 EP: (2) that Applera had become aware of the Rotor-Gene<sup>TM</sup> 3000 and Rotor-Gene<sup>TM</sup> 6000 devices on Corbett's website; (3) that the Rotor-Gene<sup>TM</sup> 3000 and Rotor-Gene<sup>TM</sup> 6000 products realize all features of claim 1 of the '562 EP; (4) that Corbett had infringed Applera's exclusive rights; and (5) that Corbett was liable for damages, must destroy its products, and pay attorney's fees.
- 19. In the letter, Applera's counsel offered Corbett an opportunity to "settle this dispute" by signing, unchanged an attached "Cease and Desist Declaration" requiring Corbett to refrain from "offering, using, putting in circulation or importing or possessing for the mentioned purposes in the Federal Republic of Germany" and "destroy" the apparatus described by the language of claim 1 of the '562 EP.
- 20. In the letter, Applera's counsel also attached a patent infringement complaint and stated that the complaint would be "made pending without further notice" should Corbett not return the signed Cease and Desist Declaration by April 17, 2008.
- 21. Corbett did not sign the Cease and Desist Declaration and on April 18, 2008, Applera filed a complaint for patent infringement with the German District Court in Dusseldorf. A copy of Applera's German patent infringement complaint against Corbett is attached hereto as Exhibit E.
- 22. Corbett currently sells and has plans to continue to sell in the United States the same Rotor-Gene<sup>TM</sup> products that Applera has accused of infringing the claims of EP '562. Corbett believes it has a right to manufacture, import, use, sell, and offer for sale its Rotor-Gene<sup>TM</sup> products in the United States.
- 23. However, based on Applera's accusations regarding the '562 EP claims and its filing of the German patent infringement lawsuit, Corbett believes that there is a real and imminent danger that Applera will sue Corbett for infringement of the nearly identical claims of the '934 patent based on its sales of the Rotor-Gene<sup>TM</sup> products in the United States.

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- 24. Corbett believes that Applera's actions regarding the '562 EP have put Corbett in the position of either risking a suit for infringement of the '934 patent by continuing to sell its Rotor-Gene<sup>TM</sup> products in the United States or abandoning the market until the '934 patent expires.
- 25. Thus, a valid and justiciable controversy regarding the patents-in-suit has arisen between Corbett and Applera that is properly presented for judicial relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

#### **FIRST CLAIM FOR RELIEF**

### (Request for Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,814,934)

- 26. Corbett realleges and incorporates herein by reference the allegations contained in Paragraphs 1 through 25.
- 27. A valid and justiciable controversy within the meaning of 28 U.S.C. § 2201 has arisen and exists between Corbett and Applera regarding the infringement of the '934 patent.
- 28. Corbett has not infringed, has not willfully infringed, is not now infringing, has not contributorily infringed, and has not induced infringement any valid and enforceable claim of the '934 patent either literally or under the doctrine of equivalents.
- 29. Applera is also estopped from asserting that the claims of the '934 patent have been infringed by Corbett because the claims of the '934 patent were so restricted and limited in scope during the prosecution of the application upon which the patent issued so as to distinguish the alleged invention from the prior art, to overcome the objections of or rejection by the examiner, and to induce the issuance of the patent that said claims cannot be construed as describing or embracing any activities, instruments, products, or methods used, promoted, or induced by Corbett.
- 30. A judicial determination and declaration of non-infringement is necessary and appropriate to resolve this controversy and so that the parties may ascertain their respective rights and duties.

#### SECOND CLAIM FOR RELIEF

#### (Request for Declaratory Judgment of Invalidity of U.S. Patent No. 6,814,934)

31. Corbett realleges and incorporates herein by reference the allegations contained in Paragraphs 1 through 30.

- 32. A valid and justiciable controversy within the meaning of 28 U.S.C. § 2201 has arisen and exists between Corbett and Applera regarding the validity of the '934 patent.
- 33. The '934 patent is invalid because it fails to satisfy the conditions and requirements for patentability as set forth in at least 35 U.S.C. §§ 101, 102, 103, and/or 112, and due to double patenting.
- 34. A judicial determination and declaration of invalidity is necessary and appropriate to resolve this controversy and so that the parties may ascertain their respective rights and duties.

### THIRD CLAIM FOR RELIEF

# (Request for Declaratory Judgment of Unenforceability of U.S. Patent No. 6,814,934)

- 35. Corbett realleges and incorporates herein by reference the allegations contained in Paragraphs 1 through 34.
- 36. A valid and justiciable controversy within the meaning of 28 U.S.C. § 2201 has arisen and exists between Corbett and Applera regarding the enforceability of the '934 patent.
- 37. The '934 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("USPTO"). Such conduct includes, but is not limited to, the applicant for the '934 patent, Russell Gene Higuchi, not disclosing the true inventorship of the '934 patent with an intent to deceive the USPTO.
- 38. On January 22, 1998, Dr. Higuchi executed a declaration submitted to the USPTO asserting that he was the sole inventor of the application that ultimately issued as the '934 patent. This inventor declaration is attached hereto as Exhibit F. As a result of this declaration, the USPTO listed Dr. Higuchi as the sole inventor of the '934 patent.
- 39. But, upon information and belief, Dr. Higuchi worked together with Dr. Gavin Dollinger at Cetus on a project to label materials with unique pieces of DNA that could be detected by amplification using the polymerase chain reaction ("PCR"). During the course of that project, a technician mistakenly added a fluorescent dye for labeling DNA called ethidium bromide to a PCR amplification tube at the beginning rather than the end of the amplification reaction.

1 40. Dr. Higuchi asserted that it was to his surprise that the ethidium bromide did not inhibit the amplification reaction. As a result, Dr. Higuchi claims to have come upon the invention of a method to detect the progress of a PCR amplification in real-time (*i.e.*, "real-time PCR").

41. Dr. Dollinger was an expert in making analytical machines used to monitor chemical reactions. Upon information and belief, Dr. Dollinger also learned of the technician's PCR amplification mistakenly performed with ethidium bromide added at the beginning. Based upon this,

Dr. Dollinger realized that a machine should be created which could act as a thermocycler and detect

fluorescence and thereby follow the PCR amplification process in real-time.

- 42. Upon information and belief, Dr. Dollinger first conceived of such a real-time PCR machine as consisting of a spectrofluorometer, which measures fluorescence, with a temperature-controlled sample chamber that could be heated and cooled. This initial design for the machine is described in the '934 patent at col. 12, lines 14-17. ("In a spectrafluorometer capable of heating and cooling a surface, or vessel, an optic fiber is not required. The optic fiber is only necessary where a thermocycler and spectrafluorometer are housed independently.")
- 43. Upon information and belief, Dr. Higuchi (or others involved in the preparation of the '934 patent application) had knowledge of Dr. Dollinger's initial design and included a description of it in the specification.
- 44. Dr. Dollinger's initial design for a real-time PCR machine fulfills the requirements of the instrument and system recited in at least claims 1 and 7 of the '934 patent.
  - 45. Claim 1 of the '934 patent requires:

An instrument for use in monitoring a nucleic acid amplification reaction comprising multiple thermal cycles, comprising:

- (a) an automated thermal cycler capable of alternately heating and cooling, and adapted to receive, at least one reaction vessel containing an amplification reaction mixture comprising a target nucleic acid, reagents for nucleic acid amplification, and a detectable nucleic acid binding agent; and
- (b) a detector operable to detect a fluorescence optical signal while the amplification reaction is in progress and without opening the at least one reaction vessel, which fluorescence optical signal is related to the amount of amplified nucleic acid in the reaction vessel.
- 46. Claim 7 of the '934 patent requires:

A system for use in monitoring a nucleic acid amplification reaction comprising multiple thermal cycles, comprising:

COMPLAINT FOR DECLARATORY JUDGMENT

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(a) at least one reaction vessel adapted to contain an amplification reaction mixture comprising a target nucleic acid, reagents for nucleic acid amplification, and a detectable nucleic acid binding agent;

(b) an automated thermal cycler capable of alternately heating and cooling such a reaction vessel, and

- (c) a detector operable to detect a fluorescence optical signal while the amplification reaction is in progress and without opening the at least one reaction vessel, which fluorescence optical signal is related to the amount of amplified nucleic acid in the reaction vessel.
- 47. Upon information and belief, Dr. Dollinger conceived of the initial design for the real-time PCR machine without Dr. Higuchi telling him what to do or supervising him. Dr. Dollinger is an inventor of at least '934 patent claims 1 and 7.
- 48. Furthermore, information regarding Dr. Dollinger's development of this initial design for a real-time PCR machine is material to the patentability of the '934 patent. However, the '934 patent and file history nowhere disclose Dr. Dollinger's conception of this initial design.
- 49. Upon information and belief, after performing some work on this initial design, Dr. Dollinger decided to pursue another design to implement a machine for real-time PCR. Dr. Dollinger next conceived of, designed, and built a machine that is the same as described in Example VIII of the '934 patent. (See, e.g., '934 patent, col. 23, lines 2-45.) This machine included a spectrafluorometer with a fiber optic connected to a PCR tube containing an amplification reaction placed in a thermocycler. The machine was capable of alternately heating and cooling the PCR tube and measuring a fluorescence optical signal while an amplification reaction was in progress. This machine fulfilled the requirements of the instrument and system recited in at least claims 1 and 7 of the '934 patent.
- 50. Upon information and belief, Dr. Dollinger conceived of, designed, and built a machine for real-time PCR the same as disclosed in Example VIII without Dr. Higuchi telling him what to do or supervising him. Dr. Dollinger is an inventor of at least '934 patent claims 1 and 7.
- 51. Furthermore, information regarding Dr. Dollinger's development of the machine of Example VIII is material to the patentability of the '934 patent. However, the '934 patent and file history nowhere disclose Dr. Dollinger's conception, design, and building of this machine for real-time PCR.